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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,650	04/21/2006	Bradley Teegarden	20750-034US1 004.US3.PCT	5391
26204 7590 06/19/2008 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER YOUNG, SHAWQUA	
			ART UNIT 1626	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,650	Applicant(s) TEEGARDEN ET AL.	
	Examiner SHAWQUIA YOUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-122 is/are pending in the application.
- 4a) Of the above claim(s) 118-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 98-122 are currently pending in the instant application. Applicants have cancelled claims 1-97 in the amendment filed on March 4, 2008.

I. *Priority*

The instant application is a 371 PCT/US03/40844, filed on December 22, 2003 which claims benefit of US Provisional Application 60/436,326, filed on December 24, 2002 and 60/464,992, filed on April 23, 2003.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on November 28, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election with traverse of Group I in the reply filed on November 5, 2007 is acknowledged. Traversal is on the ground(s) that: the restriction requirement is improper because: (a) the Office has not demonstrated that the claims lack unity of invention; (b) the groups from the election is being required are arbitrary and improper; (c) no undue burden of searching the entire scope of the invention has been established; (d) the restriction requirement is incomplete and (e) the restriction requirement is unclear.

All of the Applicants' arguments have been considered but have not been found

persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that the office has not demonstrated that the claims lack unity of invention. The Examiner stated clearly that Applicants special technical feature in formula A does not provide a contribution over the prior art in the previous Office Action (See page 8 of the Restriction Requirement). The special technical feature of the claimed invention only includes the core structure which is constant among all of the compounds embraced by formula I. The special technical feature does not include any variables and therefore the core structure which is a pyrazole ring attached to a phenyl ring and the phenyl ring is attached to an amino group.

Applicants argue that the groups from the election is being required are arbitrary and improper. The Examiner wants to point out that Applicants' claims embrace vast subject matter which comprises numerous distinct and independent inventions. The Examiner has grouped the inventions based on classification of the compounds. Applicants were given an opportunity to elect a single invention that may not be present in the groups developed by the Examiner (See page 7 of the Restriction Requirement).

Applicants argue that no undue burden of searching the entire scope of the invention has been established. However, the Examiner wants to point out that the

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compounds embraced by formula I are classified in different classes such as 544, 546, 548, etc. and consist of different inventions that are patentably distinct and independent. Therefore, different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the inventions encompassed by group I. Each Class 514, 544, 546 and 548 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety. As mentioned in the Restriction Requirement that "all compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election will be directed to nonelected subject matter and will be withdrawn from consideration under 35 USC 121 and 37 CFR 1.142(b)". Applicants did not traverse the restriction requirement.

Applicants argue that the restriction requirement is incomplete and unclear. The Examiner wants to emphasize that the claimed invention embraces vast subject matter and it would be impossible, with the limited time the Examiner is given to work on each case, to state all of the possible groups that are embraced by the formula I. As mentioned in the Restriction Requirement, the groups listed are only exemplary but not the only groups possible. The restriction requirement was not incomplete. In the situation of a 371 case, the Examiner has disclosed why the claimed invention lacks unity of invention and has listed some of the exemplary groups of the distinct and independent inventions embraced by the claimed invention in claim 98.

The Examiner wants to reemphasize that Applicants had an opportunity to elect what they considered to be a single invention but Applicants decided to elect one of the groups listed by the Examiner in the Restriction Requirement.

Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

IV. Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 98-117 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (A) or pharmaceutically acceptable salts of said compound does not reasonably provide enablement for a **solvate** or a **hydrate** of a compound of formula (A). The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary

experimentation is “undue.”

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a compound of formula (A), or a pharmaceutically acceptable salt of said compound. There is no teaching of solvates or hydrates of the compounds of Formula A in the specification.

The state of the prior art and predictability or lack thereof in the art

It is the state of the prior art that the term “solvate” found in the claims is defined as a compound formed by solvation (the combination of solvent molecules with molecules or ions of the solute. It has been estimated that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates. Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a

series of related compound (See *Vippagunta, et al.*)

The scope of “solvate” is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active *in vivo*. Solvates and hydrates cannot always be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular hydrate or solvate.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the specification or working examples present in the specification are that defines or relates to what solvates are being included in the elected invention.

The breadth of the claims

The breadth of the claims is a compound of formula A or a pharmaceutically acceptable salt, solvate or hydrate of said compound.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to what compounds form solvates with which solvents.

The level of skill in the art is high without showing or guidance as to how to make solvates of a compound of formula (A) it would require undue experimentation to figure out the solvents, temperatures and reaction times that would provide solvates of the above compounds.

To overcome this objection, Applicant should submit an amendment deleting the term "solvates".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 99, and 112-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "having formula" renders the products indefinite as the phrase "having formula" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula A that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the phrase "having formula" to read "of structure" in claims 99, 112 and 114.

V. *Objections*

Claim Objection-Non Elected Subject Matter

Claims 98-117 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

VI. *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626

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